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10/075,615

02/15/2002

Joseph C. Cauthen III

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EXAMINER

ISABELLA, DAVID J

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

07/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/075,615

Applicant(s)

CAUTHEN, JOSEPH C.

Examiner

DAVID J. ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,8-12 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,7 and 17-21 is/are rejected.
- 7) ☒ Claim(s) 1-4,7,17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election with traverse of Species 1, i.e. figure 1 in the reply filed on 4/27/2007 is acknowledged. The traversal is on the ground(s) as set forth in 37CFR 1.146 and according to MPEP § 808.01(a), election of species may be required prior to a search on the merits ... in applications containing both species claims and generic or Markush claims. Applicants respectfully submit that a search of the subject matter of all alleged species would not impose an additional burden on the Examiner. Indeed, the subject matter has already been searched, and Official Actions on the merits were previously mailed on the claims on August 29, 2003, June 3, 2004, August 24, 2005, and March 6, 2006. It is not clear how, after four substantive actions, the claims now present an undue burden on the Examiner.

. This is not found persuasive because there is nothing in MPEP section 808.01(a) and rule 37CFR1.146 that prohibits the examiner from making a restriction to various species. It is not clear what portion of rule 37CFR1.146 limits restriction to species to only occur in the first action on an application containing a generic claims. Clearly the species in each of figure 1; figure 4A;4B;4C;5A,B;6A, B;10A,B;13,18A, B;19A,b; and 21 are distinctly different and have different mechanisms of function. The simple device as illustrated in figure 1 is limited physically limited to a membrane-like device with a central reinforcing extension. The device as illustrated in figure 5A includes a membrane-like component to which a bladder is attached thereto. The in vivo mode of operation between the two devices differs and the devices are structurally

Art Unit: 3738

different and distinct. The device as illustrated in figure 18A is similar to function as that of figure 1 however there is no structural similarities between the two devices.

Likewise, the device of figure 21 is similar in operation as that of figure 5A however it is structurally similar to the device of figure 18A and not figure 5A. Since the structure of the devices are structurally distinct and have operational mode unique to the structure though they all provide similar function, the restriction to the species is proper. In so far as a serious burden on the examiner, any additional features which must be considered and searched the features are not required in all the species, a serious burden is placed on the examiner.

Claims 5,6,8-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/27/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2,3,7 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 are indefinite. Claim 2 recites that the “inside edge joins said centralized vertical extension to form a substantially horizontal plane”. It is not clear how the edge forms a horizontal plane with the extension. It appears that the extension, ie. surfaces may be joined with the extension and one or both surfaces are joined to the extension such that the surface(s) and some feature of the extension either delineate or lie in some plane.

With respect to claim 3, the angular range of “0-60” degrees does not appear to encompass the definition of “horizontal plane”. (i.e. deviation of 60 degrees from a horizontal line would not be defined as a horizontal plane.

Claim 7 is not grammatically correct. (i.e. a recess wherein said upper surface joins said centralized vertical)

Claim 17 is inaccurate. The shape should be defined according to a cross-section of the elongated extension.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21,18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al [5290217].

Schmidt et al discloses a therapeutic device providing a device comprising a biocompatible material such that said material forms a bridge providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers tissue and the device having means for acute securement of said device to said disc annulus (i.e. sutures, staples, etc). While Schmidt et al is silent to the repair vertebral tissue by the placement of the device in and across an aperture in the intervertebral disc wall, the device of Schmidt is capable of placement and function in the intervertebral disc wall.

Claims 18-20, the device of Schmidt et al is a fiber mesh that is bioabsorbable and has properties that facilitates regeneration of new tissues.

Allowable Subject Matter

Claims 1,2,3,4,7 and 17 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

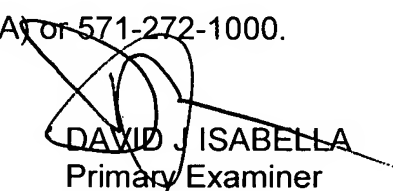
Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone

Art Unit: 3738

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
7/1/2007